REMARKS

Claims 2, 7, 14, and 15 are canceled, herewith. Claim 1 has been amended to recite the elements of previous claims 2 and 15. Claim 18 has been amended to incorporate the same elements. New claim 21 has been added which incorporates the elements of claims 1, 2, and 15, but deletes the equol producing isoflavones as discussed, *infra*. Support for the new claims resides in the previous claims, in the specification, and Examples 1-8. No new matter has been added, and all amendments are made without prejudice or disclaimer.

Rejection of claims 15 and 18 under 35 U.S.C. § 112

Claims 15 and 18 has been rejected under 35 U.S.C. § 112 as being indefinite for the use of the element "soy protein material." As an initial matter, the term "soy protein material" has been incorporated into claims 1 and 21, while claim 15 has been canceled.

Although the Office Action has maintained the original rejection, Applicants note again that that the term "soy protein material" is properly recited and defined in the specification. Specifically, the specification states in paragraph [35] that "[a] soy protein material for use in accordance with the method of the present invention is a whole soybean seed, or soy protein derivatives that can be formed from whole soybeans." The M.P.E.P. states that "where an explicit definition is provided for a term, that definition will control interpretation of the term as it is used in the claim." M.P.E.P. § 2111.01 (IV). Thus, Applicants request clarification as to why this definition is purportedly unclear, especially since an unambiguous definition appears in the specification.

Rejection of claims 1-15 under non-statutory double patenting

Applicants note that although a common inventor is shared, the reference does not claim the same invention as the cited reference. Specifically, "[a] prior art reference that renders claimed subject matter obvious under 35 U.S.C. 102(e)/103(a) does not create a double patenting situation where that subject matter is not claimed in the reference patent." M.P.E.P. § 804 (III). The claims of U.S. patent 6,326,366 are drawn to incontinence treatment using a combination of estrogen and isoflavones; whereas the instant claims are drawn to the opposite invention which is treatment of incontinence using isoflavone without using estrogen. Thus, the claimed subject matter and the '366 patent claims are mutually exclusive of each other and by definition do not extend patent term. To the extent that the reference would operate as a basis for a 35 U.S.C. § 103(a) rejection, Applicants present arguments below. Thus, Applicants respectfully request withdrawal of the rejection.

Rejection of claims 1-14 and 16-17 under 35 U.S.C. § 102(b)

Claims 1-14 and 16-17 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Kelly et al. (PCT Patent Publication No. WO 98/08503). Applicants have amended independent claim 5 to incorporate the elements of "soy protein material" comprising isoflavones as recited in claim 15 and an increase of blood isoflavone concentrations to at least 50 ng/ml as recited in claim 2. The use of a composition comprising soy protein material and isoflavone to raise the blood isoflavone concentration of incontinent patients to at least 50 ng/ml or more is not taught or suggested as a therapy for incontinence by Kelly et al. Therefore, Applicants respectfully request withdrawal of the rejection.

Moreover, Kelly et al. fails to enable methods of treating incontinence with isoflavones because it fails to teach the therapeutic dose (i.e., necessary blood isoflavone concentration) for treating this particular condition. On page 9, Kelly et al. acknowledges that the dose "which is required in a therapeutic treatment will

depend on a number of factors, which include the specific application, the nature of the particular compound used, the condition being treated, the mode of administration and the condition of the patient." Although Kelly et al. lists possible ranges for treating diseases generally, it does not specify ranges for treating incontinence with any particular isoflavone. Furthermore, finding such an amount would require undue experimentation given the uncertainty and the number of factors discussed above that must be considered. Consequently, it would not be within the ordinary skill of the artisan to arrive at such a dose. As such, Applicants respectfully request withdrawal of the rejection for at least the foregoing reasons.

Rejection of claims 15 and 18-20 under 35 U.S.C. § 103(a)

Claims 15 and 18-20 have been rejected under 35 U.S.C. § 103(a) as being obvious in view of Kelly et al. (PCT Patent Publication No. WO 98/08503) and Potter et al. (U.S. Patent No. 6,326,366). As discussed *supra*, Applicants have amended independent claim 5 to incorporate the elements of "soy protein material" comprising isoflavones as recited in original claim 15 and an increase of blood isoflavone concentration to at least 50 ng/ml as recited in original claim 2. The use of a combination of soy protein material and isoflavones to raise the blood isoflavone concentration of incontinent patients to at least 50 ng/ml or more is not taught or suggested as a therapy for incontinence by either reference. Moreover, there is no guidance to one of skill in the art as to how to arrive at a method of treating incontinence according to the instant claims. Applicants are the first to show the effective dose for treating incontinence. As such, there is no teaching, suggestion, or motivation to arrive at the claimed methods, and Applicants respectfully request withdrawal of the rejections.

Finally, Applicants note that new claim 21 is drawn to the use of daidzein and formononetin for treating incontinence. Potter et al. teaches away from using these isoflavones for treating incontinence because "inclusion of phytoestrogens

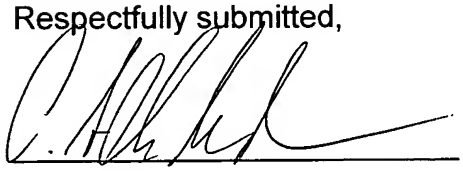
which can be metabolized to equol [i.e., daidzein and formononetin].., is at best counterproductive, and... at worst actually enhances tissue proliferation." Potter et al., col. 4, lines 1-6. Applicants teach the contrary, as well as the actual levels of blood isoflavones that are effective. Neither reference teaches the effective blood isoflavone concentrations, especially not the levels required to treat incontinence. Further, no one of skill in the art could arrive at the recited dose without undue experimentation because so many variables are present, as described *supra*. Thus, for all of these reasons, Applicant respectfully requests withdrawal of the rejections and allowance of the new claims.

Conclusion

For at least the reasons discussed above, Applicant believes that these claims define over the prior art of record and are in proper form for allowance. In accordance, Applicant respectfully requests allowance of pending claims.

If the undersigned can be of assistance to the Examiner in addressing issues to advance the application to allowance, please contact the undersigned at the number set forth below. Applicant submits that the enclosed fee necessary for consideration of this *Amendment and Response* is sufficient. Nevertheless, the Commissioner is hereby authorized to charge any additionally required fees deemed necessary for consideration of this *Amendment and Response* to Account No. 11-1110.

Respectfully submitted,



C. Allen Black, Jr.
Registration No. 53,835

KIRKPATRICK & LOCKHART NICHOLSON GRAHAM LLP
Henry W. Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222
Telephone: (412) 355-6319
Facsimile: (412) 355-6501